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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14/05/2003
C(2003) 1656

NOT FOR PUBLICATION

COMMISSION DECISION

of 14/05/2003

**amending Decision C(2000)1407 on the marketing authorization for
the medicinal product for human use**

"PegIntron - Peginterferon alfa-2b"

(Text with EEA relevance)

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC.

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of 14/05/2003

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the medicinal product for human use**

"PegIntron - Peginterferon alfa-2b"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products¹, as amended by Commission Regulation (EC) No 649/98², and in particular Article 10(2) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

- (1) The medicinal product "PegIntron - Peginterferon alfa-2b" entered in the Community register of medicinal products under Nos EU/1/00/131/031-050 authorised by Commission Decision C(2000)1407 of 25 May 2000, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.
- (2) Schering Plough Europe submitted an application to change the package leaflet on 31 January 2003 pursuant to Article 61(3) of Directive 2001/83/EC³.
- (3) The proposed changes are not connected with the contents of the summary of characteristics of the medicinal product in question.
- (4) The package leaflet as changed continues to comply with Title V of Directive 2001/83/EC
- (5) Decision C(2000)1407 should therefore be amended accordingly.

¹ OJ No L 214, 24. 8. 1993, p. 1.

² OJ L 88, 24.3.1998, p. 7.

³ OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

a) Annex III B is replaced by the Annex to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 14/05/2003

For the Commission

Erkki LIIKANEN

Member of the Commission